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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

Application Number	10/600,266
Filing Date	June 20, 2003
First Named Inventor	Fumitoshi Asai
Art Unit	1614
Examiner Name	Brian S. Kwon
Attorney Docket Number	13509.105003US

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 6,693,115	02-17-2004	Asai et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
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Attorney Docket Number	13509.105003US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Asai, Fumitoshi et al., "Platelet inhibitory activity and pharmacokinetics of prasugrel (CS-747) a novel thienopyridine P2Y12 inhibitor: A single ascending dose study in healthy humans," Platelets, vol. 17, no. 4, pp. 209-217, June 2006	
		Chen et al., "Aspirin resistance is associated with a higher incidence of myonecrosis after nonurgent percutaneous coronary intervention despite clopidogrel pretreatment," J Am Coll Cardiol, 43:1122-6, 1125 (2004)	
		FDA Cardiovascular and Renal Drugs Advisory Committee, Slide Presentation and Transcript of Meeting, February 3, 2009, available at << <a href="http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm125999.htm">http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm125999.htm</a> >>	
		Goodman and Gilman, The Pharmacological Basis of Therapeutics, Fifth Edition, p. 25-26, 1975	
		Herbert, J.M. et al., "The anti-aggregating and antithrombotic activity of ticlopidine is potentiated by aspirin in the rat," Thromb. Haemost., vol. 76, pp. 94-98, 1996	
		Herbert, J.M. et al., "The anti-aggregating and antithrombotic activity of clopidogrel is potentiated by aspirin in several experimental models in the rabbit," Thromb. Haemost., vol. 80, pp. 512-518, 1998	
		Ikeda, "Preface: Antiplatelet Therapy- An Update," Haemostasis, vol. 30, Suppl. 3, 2000, p. 1	
		Jakubowski, J.A. et al., "A multiple dose study of prasugrel (CS-747), a novel thienopyridine P2Y12 inhibitor, compared with clopidogrel in healthy humans," British Journal of Clinical Pharmacology, vol. 63, no. 4, pp. 421-430, October 31, 2006	
		Jarvis et al., "Clopidogrel: A Review of its Use in the Prevention of Atherothrombosis," Drugs, 60(2):347-377, August 2000, Abstract	
		Jernberg, Tomas et al., "Prasugrel achieves greater inhibition of platelet aggregation and a lower rate of non-responders compared with clopidogrel in aspirin-treated patients with stable coronary artery disease," European Heart Journal, vol. 27, pp. 1166-1173, 2006	

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		Lev et al., "Aspirin and Clopidogrel Drug Response in Patients Undergoing Percutaneous Coronary Intervention," Journal of the American College of Cardiology, 47(1):27-33 (2006)	
		Matsushima, Nobuko et al., "Platelet inhibitory activity and pharmacokinetics of prasugrel (CS-747) a novel thienopyridine P2Y12 inhibitor: A multiple-dose study in healthy humans," Platelets, vol. 17, no. 4, pp. 218-226, June 2006	
		PLAVIX® Prescribing Information, "Dosage and Administration," revised May 2009	
		Sacco et al., "Update on Antiplatelet Therapy for Stroke Prevention," Arch. Intern. Med., 160, June 12, 2000, 1579-1582, Abstract	
		Steinhubl, "Antiplatelet Agents in Cardiology: The Choice of Therapy," Ann. Thorac. Surg, 70:S3-8, 2000, presented Jan. 22-23, 1999	
		TICLID® Prescribing Information, revised March 2001	
		Van de Graaff, "Antiplatelet medications and their indications in preventing and treating coronary thrombosis," Annals of Medicine, 32(8), November 2000, p. 561-571, Abstract	
		Van de Graaff et al., "Variable Interindividual Responses to Antiplatelet Therapies- Do They Exist, Can We Measure Them, and Are They Clinically Relevant?" Heart Drug, 1(1):35-43 (2001), available online August 2000	
		Weerakkody, Govinda J. et al., "Comparison of Speed of Onset of Platelet Inhibition After Loading Doses of Clopidogrel Versus Prasugrel in Healthy Volunteers and Correlation With Responder Status," Am J Cardiol, vol. 100, pp. 331-336, 2007	

Examiner Signature	/Brian Yong Kwon/	Date Considered	11/21/2009
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